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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/042,930	10/18/2001	Markus Seyfried	GC582-C1	5320
5100	7590	08/19/2004	EXAMINER	
GENENCOR INTERNATIONAL, INC. ATTENTION: LEGAL DEPARTMENT 925 PAGE MILL ROAD PALO ALTO, CA 94304			STEADMAN, DAVID J	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/042,930

**Applicant(s)**

SEYFRIED ET AL.

**Examiner**

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,46-53,57-59 and 62-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,46-53,57-59 and 62-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/18/01, 01/24/02</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Status of the Application***

[1] A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on July 07, 2004 has been entered.

[2] Claims 1-3, 46-53, 57-59, and 62-65 are pending in the application.

[3] Applicant's amendment to the claims, filed July 07, 2004, is acknowledged.

[4] Applicants' arguments filed July 07, 2004 have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35, U.S. Code not included in the instant action can be found in a prior Office action.

### ***Information Disclosure Statement***

[6] Receipt of information disclosure statements (IDSs), filed October 18, 2001 and January 24, 2002, is acknowledged. All references cited in the IDSs, with the exception of references AO, AV, and BE of the IDS filed January 24, 2002, have been considered by the examiner. A copy of each IDS is attached to

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the instant Office action. References AO, AV, and BE have not been considered as there is no date of public availability provided for these references as required by 37 CFR 1.98.

### ***Specification/Informalities***

[7] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 121 as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 121 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. *If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.* It is noted that non-provisional application 09/405,692, to which applicants claim domestic priority, is now abandoned.

### ***Deposit Requirement***

[8] It is noted that the instant invention employs a novel microorganism described in the specification as ATCC Deposit Number PTA-548. Applicants

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state the deposit has been made in accordance with the Budapest Treaty (see page 37 of the instant specification). Applicants have previously provided a statement of public availability of ATCC Deposit Number PTA-584 as Paper No. 18 in parent application 09/405,692. However, no statement of public availability of the deposit has been filed in the *instant application*. In order to satisfy the biological deposit requirements, applicants should provide a statement that all restrictions upon availability to the public will be irrevocably removed upon granting of the patent.

#### ***Oath/Declaration***

[9] The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02. The oath or declaration is defective because: Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

#### ***Claim Rejections - 35 USC § 112, Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[10] Claim(s) 1-3, 46-53, 57-59, and 62-65 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claims 1 (claims 2-3, 46-53, 57-59, and 64-65 dependent therefrom) and 62 (claim 63 dependent therefrom) are indefinite in the recitation of "strain of *Caloramator*," "strain of *Thermobrachium*," and "strain of *Caloramator viterbiensis*" as the specification fails to specifically define those identifying characteristics that distinguish a "strain of *Caloramator*," "strain of *Thermobrachium*," and "strain of *Caloramator viterbiensis*" from other thermophilic bacterial organisms. The specification discloses many properties of *Caloramator viterbiensis* strain JW/MS-VS5 (pages 28-34) and the claims recite various properties that are required of the thermophilic strains. However, it is unclear as to which of the disclosed/recited properties are necessary for inclusion of a "strain of *Caloramator*," "strain of *Thermobrachium*," and "strain of *Caloramator viterbiensis*" which is distinct from other thermophilic strains that are considered to be within this class of organisms. In other words, what characteristics distinguish a "strain of *Caloramator*," "strain of *Thermobrachium*," and "strain of *Caloramator viterbiensis*" from other thermophilic strains? As such, the scope of *Caloramator*, *Thermobrachium*, or *Caloramator viterbiensis* strains that are encompassed by the terms "strain of *Caloramator*," "strain of *Thermobrachium*," and "strain of *Caloramator viterbiensis*" is unclear.

### ***Claim Rejections - 35 USC § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which

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it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**[11]** Claims 1-3, 46-53, 57-59, 62-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 1 (claims 2-3, 46-53, 57-59, and 64 dependent therefrom) recites the limitations of "a temperature range for growth at pH 6.0 of 33 to 60°C." Claims 1 and 62 (claim 63 dependent therefrom) recite the limitation "a pH range for growth from 5.0 to 7.8 at a temperature of 25°C." Claim 65 recites the limitation "wherein the guanine-plus-cytosine (G+C) content of the genomic DNA of the thermophilic strain is 32 mol% measured by high-performance liquid chromatography. Applicants cite page 7, lines 17-30, page 8, lines 4-9, and page 34, Table 2 of the specification as providing support for the new limitations. Regarding claims 1 and 62, the examiner can find no support for these limitations at pages 7-8 of the specification. Also, the examiner can find no support for any strain of *Caloramator* or *Thermobrachium* having a G+C content of 32 mol%. Support for a thermophilic organism having G+C content of 32 mol% can only be found for strain JW/MS-VS5. Applicants are invited to direct the examiner's attention to supporting disclosure for these limitations in the specification, claims, and/or drawings as originally filed.

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**[12]** In view of applicants' amendment to the claims to recite additional distinguishing characteristics of the recited genus of thermophilic strains of *Caloramator*, *Caloramator viterbiensis*, or *Thermobrachium*, the written description rejection of claims 1-4, 46-53, 57-59, and 62 under 35 U.S.C. 112, first paragraph, as set forth in item [7] of the Office action mailed May 16, 2003 is withdrawn.

**[13]** The scope of enablement rejection of claims 1-3, 46-53, 57-59, and 62-65 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record as set forth in item [8] of the Office action mailed May 16, 2003 and for the reasons stated below.

**[14]** RESPONSE TO ARGUMENTS: Applicants acknowledge that the specification discloses only a single working example of the recited genus of thermophilic strains of *Caloramator*, *Caloramator viterbiensis*, or *Thermobrachium*. Although only a single working example is disclosed, applicants argue the specification teaches how to make and use the full scope of claimed methods using only routine experimentation. Applicants' argument is not found persuasive.

The specification, while being enabling for a method of converting glycerol to 1,3-propanediol by culturing the microorganism having ATCC Accession Number PTA-584 under conditions such that 1,3-propanediol is produced, does not reasonably provide enablement for the broad scope of claimed methods using the vast number of thermophilic strains of *Caloramator*, *Caloramator viterbiensis*, or *Thermobrachium* broadly encompassed by the claims. The



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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

It is the examiner's position that undue experimentation would be required for a skilled artisan to make and/or use the entire scope of the claimed invention. Factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands* (858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)) as follows: (A) The breadth of the claims; (B) The nature of the invention; (C) The state of the prior art; (D) The level of one of ordinary skill; (E) The level of predictability in the art; (F) The amount of direction provided by the inventor; (G) The existence of working examples; and (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure. See MPEP § 2164.01(a). The Factors most relevant to the instant rejection are addressed in detail below.

- The claims are overly broad in scope: The claims are so broad as to encompass a method of converting glycerol to 1,3-propanediol using a vast number of mutants and variants of the microorganism having ATCC Accession Number PTA-584, including strains that are naturally-occurring and non-naturally occurring. The broad scope of claimed methods is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of thermophilic strains of *Caloramator*, *Caloramator viterbiensis*, or *Thermobrachium* broadly encompassed by the claims. In this case the disclosure

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is limited to a method of converting glycerol to 1,3-propanediol by culturing the microorganism having ATCC Accession Number PTA-584 under conditions such that 1,3-propanediol is produced.

- The lack of guidance and working examples: The specification provides only a single working example of the scope of claimed methods, i.e., a method of converting glycerol to 1,3-propanediol by culturing the microorganism having ATCC Accession Number PTA-584 under conditions such that 1,3-propanediol is produced. Other than the microorganism having ATCC Accession Number PTA-584, the specification provides no other working examples of thermophilic microorganisms that can be used for the claimed method. The claims broadly encompass a vast number of variants and mutants of ATCC Accession Number PTA-584, however, the specification provides no specific guidance as to how one alters the 16S rDNA of the microorganism having ATCC Accession Number PTA-584 without altering the biological characteristics that are required to practice the claimed methods, e.g., the ability to convert glycerol to 1,3-propanediol and having specific temperature and pH ranges for growth. Further, it is noted that the 16S rDNA sequence is disclosed as being "almost complete" (page 32, bottom of the specification).

- The high level of unpredictability in the art: Stackebrandt (cited in the Office action mailed 12/13/02) teaches that only a minor change in the 16SrDNA sequence of a prokaryotic organism can significantly alter the physiological and biochemical properties of the microorganism (page7). These teachings are

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undisputed by applicants. As such, a skilled artisan would recognize the high level of unpredictability in altering the 16S rDNA sequence of a microorganism with an expectation that the resulting microorganism will maintain the desired biological characteristics.

- The amount of experimentation required is undue: While methods of generating variants and mutants of a microbial strain are known in the art, e.g., UV or chemical mutagenesis, it is not routine in the art to screen for all variants and mutants of a microbial strain having any physiological or biochemical alteration(s) as encompassed by the claims.

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability as evidenced by the prior art, and the amount of experimentation that is required, it is the examiner's position that undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicant has not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir, 1988).

### ***Double Patenting***

[15] The provisional double patenting rejections as set forth in items [9] and [10] of the Office action mailed December 13, 2002 have been withdrawn in the Office action mailed May 16, 2003. Thus, applicants' request to hold the rejections in abeyance until patentable subject matter is agreed upon in the instant application is rendered moot.

### ***Conclusion***

[16] Status of the claims:

- Claims 1-3, 46-53, 57-59, and 62-65 are pending.
- Claims 1-3, 46-53, 57-59, and 62-65 are rejected.
- Claims 1-3, 46-53, 57-59, and 62-65 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs, set forth in this Office action.
- No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (571) 272-0942. The Examiner can normally be reached Monday-Friday from 7:00 am to 3:30 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The FAX number for submission of official papers to Group 1600 is (703) 872-9306. Draft or informal FAX communications should be directed to (571) 273-0942. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman  
Patent Examiner

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